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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,440	02/05/2004	Michal Daniely	26003	3178

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MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,440	DANIELY ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72,73 and 82-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72,73 and 82-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

1. The species election filed February 15, 2010, is acknowledged and has been entered. Applicant has elected a high nucleus to cytoplasm (N/C) ratio as the species of morphological abnormality and polyploidy of chromosome 3 as the species of chromosomal abnormality. However, after further consideration of the prior art, an enlarged nucleus, a considerable dark appearance of a cell and an irregular nuclear border as compared to a transitional epithelial cell with a normal morphology have been rejoined with the elected species of morphological abnormality and polyploidy of chromosome 7, polyploidy of chromosome 17 and loss of the 9p21 locus have been rejoined with the elected species of chromosomal abnormality. No other species or Groups have been rejoined.

2. Claims 72-73 and 82-92 are pending in the application and are under examination.

Information Disclosure Statement

3. The references cited in the information disclosure statement filed on April 21, 2010, have been considered.

Notably, while considered, the citation of the search report and other foreign office communications were crossed out as these citations do not conform to the information disclosure statement requirements because, for example, they do not establish these communications as publicly available documents (see MPEP 609).

Grounds of Rejection Withdrawn

4. Unless specifically reiterated below, Applicant's amendment and/or arguments filed October 7, 2009, have obviated or rendered moot the grounds of rejection set forth in the previous Office action mailed June 10, 2009.

Grounds of Rejection Maintained

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 72, 73, 82, 83, 85 and 87-92 under 35 U.S.C. 102(b) as being anticipated by Inoue et al (Urol Res. 28:57-61, 2000), is maintained.

At page 8 of the amendment filed October 7, 2009, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

As amended, the claims herein recite methods comprising:

(a) staining nucleated cells of a urine sample using a stain selected from the group consisting of May-Grunwald-Giemsa, Giemsa, Papanicolau and Hematoxylin-Eosin to thereby obtain stained nucleated cells;

(b) imaging said stained nucleated cells resultant of steps (a) so as to obtain images of said stained nucleated cells, and;

(c) identifying by said stain in said images of step (b) a single cell having a morphological abnormality which indicates that said single cell is suspicious as a transitional cell carcinoma cell

(d) staining said stained nucleated cells resultant of step (a) using fluorescent in situ hybridization (FISH) to thereby obtain stained nucleated cells stained with FISH, and; subsequently;

(e) imaging said nucleated cells stained with FISH resultant of step (d) so as to obtain images of said nucleated cells stained with FISH; and subsequently;

(f) identifying by said FISH in said images of step (e) a chromosomal abnormality which indicates that said single cell is a transitional cell carcinoma cell in the same said single cell identified in step (c) having said morphological abnormality; (see claim 72)

or methods comprising:

(a) obtaining a urine sample from the subject;

(b) staining nucleated cells of said urine sample using a stain selected from the group consisting of May-Grunwald-Giemsa, Giemsa, Papanicolau and Hematoxylin-Eosin to thereby obtain stained nucleated cells;

(c) imaging said stained nucleated cells resultant of steps (b) so as to obtain images of said stained nucleated cells, and;

(d) identifying by said stain in said images of step (c) a single cell having a morphological abnormality which indicates that said single cell is suspicious as a transitional cell carcinoma cell

(e) staining said stained nucleated cells resultant of step (b) using fluorescent in situ hybridization (FISH) to thereby obtain stained nucleated cells stained with FISH, and; subsequently;

(f) imaging said nucleated cells stained with FISH resultant of step (d) so as to obtain images of said nucleated cells stained with FISH; and subsequently;

(g) identifying by said FISH in said images of step (f) a chromosomal abnormality which indicates that said single cell is a transitional cell carcinoma cell in the same said single cell identified in step (d) having said morphological abnormality; (see claim 73). Claims 83 and 85 are further drawn to obtaining the urine samples by catheterization. Claims 87-92 further recite that the morphological abnormality is a considerable dark appearance of a cell or an irregular nuclear border as compared to a transitional epithelial cell with a normal morphology and that the chromosomal abnormality is polyploidy of chromosome 7 or loss of the 9p21 locus.

Starting at page 10 of the response filed October 7, 2009, Applicant appears to be arguing that Inoue et al do not anticipate the claims methods because:

> "[The] Examiner has mis-interpreted the art of Inoue et al. in stating that Inoue et al. identify a chromosomal abnormality (chromosome 9 monosomy) in the same said

single cells identified in step (c) as having a morphological abnormality stained by Giemsa, since although Inoue et al., stained the exfoliated cells (from bladder washings at cystoscopy) by Giemsa in order to identify clusters of transitional cells (Inoue Page 57, right column, 3ra paragraph), the identification of morphologically abnormal cells (such as class 5 cells) was performed on another sample of voided urine obtained before cystoscopy (Inoue Page 58, right column, lines 9-11) and not on the same exfoliated cells analyzed by FISH.

It should be noted that since exfoliated urine samples include clusters of cells (in which the boundaries between cells are not clear) Inoue T., et al. did not even attempt to perform cytology analysis on the exfoliated clusters stained by Giemsa. Moreover, the FISH analysis in Inoue was based on counting the number of signals in about 100 nuclei in the clusters regardless of their morphological characteristics (Inoue, Page 58, bridging paragraph), and not in a cell having a morphological abnormality which indicates that the cell is suspicious as a transitional cell carcinoma (TCC) cell as in the currently amended claimed invention.

Thus, one of ordinary skills in the art, when viewing the teachings of Inoue et al., could not have been motivated to identify transitional cell carcinoma cells from the Giemsa and FISH stained exfoliated cells of Inoue et al., since even Inoue et al. based their cytology analysis (which determines the presence or absence of morphologically abnormal cells) on another urine sample obtained from voided urine and not on the Giemsa-stained exfoliated cells which were analyzed by FISH".

In response, these arguments are not found persuasive because while the teachings of Inoue et al also performed cytology on voided urine, the teachings of Inoue et al establish that the same single cells obtained via exfoliated urine samples obtained by catheterization comprise both single cells having a morphological abnormality of a transitional cell carcinoma cell stained by Giemsa and the same single cells having a chromosomal abnormality of a transitional cell carcinoma stained by FISH. Notably, as set forth in Figure 2a and 2b, Giemsa stained single cells obtained via exfoliated urine samples are identified as having morphological abnormalities such as a considerable dark appearance of a cell or an irregular nuclear border as compared to a transitional epithelial cell with a normal morphology (see Figure 1a for transitional epithelial cells with normal morphology) and those same single cells are identified as having

chromosomal abnormalities, i.e., loss of chromosome 9, which includes loss of the 9p21 locus since an entire chromosome 9 is lost. In this case, the description of Figure 2b explicitly states that the same nuclei in the same cells are stained by FISH as those stained by Giemsa. Similarly, Figures 3a and 3b display Giemsa stained single cells obtained via exfoliated urine samples that are identified as having morphological abnormalities such as a considerable dark appearance of a cell or an irregular nuclear border as compared to a transitional epithelial cell with a normal morphology (see Figure 1a for transitional epithelial cells with normal morphology) and those same single cells are identified as having polyploidy of chromosome 7. In this case, the description of Figure 3b explicitly states that the same nuclei are stained by FISH as those stained by Giemsa. Accordingly, the methods of Inoue et al which stain and identify the same single cells as having both morphological abnormalities as stained by Giemsa and chromosomal abnormalities as stained by FISH are materially and manipulatively indistinguishable from the claimed process.

Furthermore, while Applicant points out that the FISH analysis in Inoue was based on counting the number of signals in about 100 nuclei in cells regardless of their morphological characteristics (Inoue, Page 58, bridging paragraph), and not only in a cell having a morphological abnormality which indicates that the cell is suspicious as a transitional cell carcinoma (TCC) cell as in the currently claimed invention, this argument is not found persuasive because as set forth in Figures 2 and 3 Inoue et al identify the same cells as having morphological and chromosomal abnormalities in their exfoliated urine samples. Notably, the claims recite a step of identifying by said FISH in said images of step (e) or (f) a chromosomal abnormality which indicates that said single cell is a transitional cell carcinoma cell in the same said single cell identified in step (c) or (d) having said morphological abnormality which is performed by Inoue et al as evidenced by Figures 2 and 3. In this case, it is immaterial whether other nuclei without morphological abnormalities are also imaged by FISH as the claims recite open language "i.e., comprising" and do not exclude monitoring of other nuclei. Notably, as set forth in the claimed methods, a plurality of cells are stained (see step a) so it is apparent that multiple single cells having both the recited morphological abnormalities

and the recited chromosomal abnormalities may be stained and identified by the claimed methods.

Therefore, for these reasons and the reasons previously set forth, and after careful and complete consideration of Applicant's response, the rejection of claims 72, 73, 82, 83, 85-92 under 35 U.S.C. 102(b) as being anticipated by Inoue et al, is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The rejection of claims 72, 73, 84 and 86 under 35 U.S.C. 103(a) as being unpatentable over Inoue et al (Urol Res. 28:57-61, 2000), in view of US Patent 6,418,236 (Ellis et al, July 9, 2002, of record), is maintained.

At page 10 of the amendment filed October 7, 2009, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Claims 72 and 73 are described supra. Claims 84 and 86 are further drawn herein to said imaging being effected using an automated cell imaging device capable of at least dual imaging.

Starting at page 11 of the response filed October 7, 2009, Applicant reiterates the arguments presented against Inoue et al and concludes that since neither Inoue et al nor US Patent 6,418,236 teach identifying the same single cell as having both a morphological abnormality and a chromosomal abnormality that the claimed invention is not obvious.

In response, the Examiner incorporates the above response to the arguments against Inoue et al herein. Since Inoue et al teach identifying the same single cell as having both a morphological abnormality and a chromosomal abnormality (see Figures 1-3) Applicant's arguments are not persuasive and the rejection applies for the reasons of record as presented in the previous office action.

Accordingly, after careful and complete consideration of Applicant's response, the rejection of claims 72, 73, 84 and 86 under 35 U.S.C. 103(a) as being unpatentable over Inoue et al in view of US Patent No. 6,418,236 is maintained.

10. The rejection of claims 72, 73, 84 and 86 under 35 U.S.C. 103(a) as being unpatentable over Inoue et al (Urol Res. 28:57-61, 2000), in view of Kaplinsky (43rd ASH Annual Meeting, Blood, 98(Part 2):348b, 2001, IDS filed 4/9/08), is maintained.

At page 11 of the amendment filed October 7, 2009, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Claims 72 and 73 are described supra. Claims 84 and 86 are further drawn herein to said imaging being effected using an automated cell imaging device capable of at least dual imaging.

Starting at page 12 of the response filed October 7, 2009, Applicant reiterates the arguments presented against Inoue et al and concludes that since neither Inoue et al nor Kaplinsky teach identifying the same single cell as having both a morphological abnormality and a chromosomal abnormality that the claimed invention is not obvious.

In response, the Examiner incorporates the above response to the arguments against Inoue et al herein. Since Inoue et al teach identifying the same single cell as having both a morphological abnormality and a chromosomal abnormality (see Figures 1-3) Applicant's arguments are not persuasive and the rejection applies for the reasons of record as presented in the previous office action.

Accordingly, after careful and complete consideration of Applicant's response, the rejection of claims 72, 73, 84 and 86 under 35 U.S.C. 103(a) as being unpatentable over Inoue et al in view of Kaplinsky is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

11. Claims 72, 73, 87 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al (Urol Res. 28:57-61, 2000), in view of Brown (Urol. Clin. NA., 27(1):25-37, 2000).

Claims 72 and 73 are described supra. Claims 87 and 88 are further drawn herein to said morphological abnormality being a high nucleus to cytoplasm (N/C) ratio or an enlarged nucleus.

Inoue et al teach that which is set forth in the above rejection of claims 72 and 73 under 35 U.S.C. 102(b).

While Inoue et al teach methods of staining, imaging and identifying the same single cells from an exfoliated urine sample obtained via catheterization as having considerable dark appearance or an irregular border by Giemsa morphological staining as compared to normal transitional cells and staining by FISH to identify chromosomal abnormalities, Inoue et al does not expressly teach said morphological abnormality being a high nucleus to cytoplasm (N/C) ratio or an enlarged nucleus.

This deficiency is made up for in the teachings of Brown. Brown teaches that other morphological abnormalities that identify transitional cells as suspicious as transitional carcinoma cells include cells with a high nucleus to cytoplasm (N/C) ratio and cells that are enlarged and identifying such abnormalities with a Papanicolau stain. Notably, as Brown teaches enlarged cells and cells with a high nucleus to cytoplasm (N/C) ratio, Brown is deemed to inherently teach an enlarged nucleus as another morphological abnormality that make transitional cells suspicious as transitional carcinoma cells since a high nucleus to cytoplasm (N/C) ratio in an enlarged cell inherently results in an enlarged nucleus (see entire document, e.g., page 27).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to predictably substitute the morphological abnormalities taught by Brown in the methods of Inoue et al to identify single cells from a urine sample having a high nucleus to cytoplasm (N/C) ratio or an enlarged nucleus and a chromosomal abnormality to identify the same single cells as transitional cell carcinoma cells in view of these references as a whole. In this case, one of skill in the art would have appreciated that there are multiple art-recognized morphological abnormalities that identify transitional cells as suspicious as transitional carcinoma cells and would have considered such art-recognized morphological abnormalities as obvious variants of each other which can be predictably substituted one for the other in methods to identify the same single cells as transitional cell carcinoma cells. Furthermore, because these morphological abnormalities were all known in the art to identify transitional cells as suspicious as transitional cell carcinoma cells and because methods of imaging the same single cells were known in the art, one of skill in the art clearly would have a reasonable expectation of success in identifying

transitional cell carcinoma cells from a urine sample, by such methods, in view of the references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

12. Claims 72, 73 and 89-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al (Urol Res. 28:57-61, 2000, of record), in view of Sokolova et al (J. Mol. Diag., 2(3):116-123, 2000, of record).

Claims 72 and 73 are described supra. Claims 89-92 are further drawn herein to said chromosomal abnormality being a polyploidy of chromosome 3, chromosome 17 or loss of 9p21 locus.

Inoue et al teach that which is set forth in the above rejection of claims 72 and 73 under 35 U.S.C. 102(b).

While Inoue et al teach methods of staining, imaging and identifying the same single cells from an exfoliated urine sample obtained via catheterization as having a morphological abnormality by Giemsa morphological staining as compared to normal transitional cells and staining by FISH to identify polyploidy of chromosome 7 and loss of chromosome 9 which includes loss of the 9p21 locus, Inoue et al does not expressly teach FISH stains that identify polyploidy of chromosome 3 and chromosome 17 in transitional carcinoma cells and do not teach a FISH stain that is directed at the 9p21 locus to identify loss of 9p21 in transitional carcinoma cells.

This deficiency is made up for in the teachings of Sokolova et al. Sokolova et al teach that other chromosomal abnormalities in transitional carcinoma cells include polyploidy of chromosome 3, polyploidy of chromosome 17 and loss of 9p21 and FISH stains to identify such abnormalities in cells obtained from a urine sample (see entire document, e.g., page 116 and 118).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to predictably substitute the chromosomal abnormalities taught by Sokolova et al in the methods of Inoue et al to identify single cells from a urine sample having a morphological abnormality and

polyploidy of chromosome 3, polyploidy of chromosome 17 or loss of 9p21 to identify the same single cells as transitional cell carcinoma cells in view of these references as a whole. In this case, one of skill in the art would have appreciated that there are multiple art-recognized chromosomal abnormalities that identify transitional cells as transitional carcinoma cells and would have considered such art-recognized chromosomal abnormalities as obvious variants of each other which can be predictably substituted one for the other in methods to identify the same single cells as transitional cell carcinoma cells. Furthermore, because these chromosomal l abnormalities were all known in the art to identify transitional cells as transitional cell carcinoma cells and because methods of imaging the same single cells were known in the art, one of skill in the art clearly would have a reasonable expectation of success in identifying transitional cell carcinoma cells from a urine sample, by such methods, in view of the references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

13. No claim is allowed.

14. The prior art previously made of record and not relied upon is considered pertinent to applicant's disclosure. Halling et al (of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with FISH stains. Bubendorf et al (of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with standard Papanicolaou stain or FISH stains. Darzynkiewicz et al (of record) discloses an automated cell-imaging device capable of dual imaging. Shimoni et al (of record) discloses an automated cell-imaging device capable of dual imaging of cells stained with a May-Grunwald-Giemsa stain and FISH probes. Boon et al (of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with a Giemsa stain or a Papanicolaou stain. Otto et al (of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing

bladder cancer in cells stained with a Hematoxylin stain and an Eosin stain. US Patents 6,174,681 (2001), 6,376,188 (2002) and 7,232,655 (2007) (all Halling et al, of record) disclose a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in the same single cells stained with a morphological stain, such as DAPI and FISH stains. Placer et al (Eur. Uro. 42:547-552, 2002, of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with standard Papanicolaou stain or FISH stains. Dalquen et al (Can. Cyto. 96:374-379, 2002, of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in cells stained with standard Papanicolaou stain or FISH stains. Mezzelani et al (Cyto. 13:317-325, 2002, of record) discloses a method of identifying transitional cell carcinoma cells and diagnosing bladder cancer in the same single cells stained with DAPI and FISH stains.

15. Applicant's amendment necessitated the new ground(s) of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
April 20, 2010